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Attention: Beverly Friedman

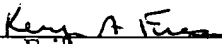
Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 6,001,876. The application was filed on February 25, 2005, under 35 U.S.C. § 156. It is noted that the patent term extension application for U.S. Patent No. 6,001,876 is based on NDA No. 21-734.

Another patent term extension application for U.S. Patent No. 6,197,819 has been filed on the approved product Lyrica® relating to NDA No. 21-446.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to Mary C. Till at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).


Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Karen DeBenedictis
Warner-Lambert Company LLC
2800 Plymouth Road, 016/410E/PAT/6
Ann Arbor, MI 48105

RE: Lyrica® (pregabalin)
FDA Docket No. 2006E-0005